

## **AMENDMENTS TO THE SPECIFICATION:**

Please amend page 1, paragraph 3, to read as follows:

### **FIELD OF THE INVENTION**

The present invention relates generally to [treatment of medical related conditions] the field of medicine and, more particularly, to the treatment of retinitis pigmentosis and the like.

Please amend page 1, paragraph 4, to read as follows:

### **BACKGROUND OF THE INVENTION**

Retinitis pigmentosis is a disease of the retina that ha[ving]s many different pathological manifestations. Notably, [I]t [can] not only causes restriction of [the] a patient's field of vision, but also increas[ing]ed difficulty in adapting to the dark and to penumbra, when it affects the peripheral zones of the retina, ~~which.~~ Generally speaking, this is because the peripheral zones accommodate a greater part of the rod cells that make vision in penumbra and perception of movement in the lateral zones possible. Alternatively or concurrently, [it] retinitis pigmentosis may lead to loss of central vision, when the cone cells are the ones that are affected by the disease and, thereby, [to] undergo [modification] deterioration. The rate at which the illness progresses varies from one patient to another. [Generally speaking] Overall, however, retinitis pigmentosis is an insidious disease that most often manifests itself in youth, especially children.

Please amend from after paragraph 4 on page 1 to before the first full paragraph on page 2 to read as follows:

The cause(s) of this infirmity are presently unknown and, ~~consequently~~, there is not yet a cure. The only information known for certain about the disease, ~~that is at the disposal of experts~~, concerns [a] its possible genetic origin ~~of retinitis pigmentosis, which. More particularly, retinitis pigmentosis~~ is believed to be [transmitted] passed, in part, by heredity from generation to generation, following mechanisms ~~that are~~ known [generally] to geneticists. Most forms of retinitis pigmentosis are hereditary and three transmission modalities have been identified thus far: dominantly autosomal, recessively autosomal and X-linked or bound up with by sex [(X-linked)].

Please amend page 2, first full paragraph, to read as follows:

The [principal] main symptoms of the [illness] disease are crepuscular and nocturnal blindness, i.e., difficulty of seeing when [the] lighting conditions are poor, and problems [of] adaptati[o]ng from well-lit to dark environments or vice versa. This phenomenon is due to the fact that, at least in ~~the greater part~~ a majority of cases, attack in the early development phases of the illness is concentrated on the rod cells. Other [typical] common symptoms are [the] a reaction to excessively strong light (dazzlement), a gradual narrowing of the visual field, which manifests itself in the form of difficulty in

perceiving objects situated [on] to either side of the patient, or stumbling over steps or other low obstacles, eventually ~~arriving at~~ resulting in complete blindness.

Please amend page 2, second full paragraph, to read as follows:

The course [of] followed by the illness is of extremely variable duration, but is always gradual and ultimately leads to [disablement] disability. In the greater part of cases, however, the [previously described] symptoms described previously become aggravated, the visual field becomes more and more restricted and eventually closes completely. Other complaints tend to appear, [among them] dazzlement being among them, ~~incapacity of~~ as well as the inability to distinguish[ing] colo[u]rs, and a particular form of cataract. In many cases, the final outcome is, unfortunately, [absolute] total blindness.

Please amend page 2, third full paragraph, to read as follows:

~~For the purpose of diagnosing the illness it is usual~~ In diagnosing retinitis pigmentosis, it is common to rely on [such] tests such as examination of the fundus of the eye, examination of the visual field, electroretinograms, fluorangiography, and visus examination:

Please amend from after the third full paragraph on page 2 to before the first full paragraph on page 3 to read as follows:

- [examination of] the fundus of the eye [aims at] is examined to assess[ing] the condition of the retina and to look for the presence of [the characteristic] pigment spots on the retinal surface characteristic of the illness, which [in the illness] assume an [characteristic] “osteoblast-like” appearance. ~~Though they present the same symptoms;~~ It is noted that some rare forms of retinitis pigmentos[a]is are not [however] characterized by spots on the fundus of the eye, though they present the same symptoms otherwise;

Please amend page 3, first full paragraph, to read as follows:

- examination of the visual field makes it possible to evaluate the sensitivity of [the] various parts of the retina to light stimuli. It [will be] is considered particularly useful to have [an] objective documentation of the difficulty in visual perception experienced by the patient;

Please amend page 3, second full paragraph, to read as follows:

- [the] an electroretinogram (ERG) [consists of] record[ing]s the electrical activity of the retina in response to particular light stimuli, ~~thus making possible distinct valuations of~~ thereby enabling the functionality of the two different types of photore-

ceptors (i.e. cone cells and rod cells) to be evaluated. The electroretinogram is [a] very important [examination] for diagnosing retinitis pigmentos[a]is, because – even when the illness is in its initial stages – the resulting trace [is] almost always is either very flat or [altogether] absent altogether;

Please amend page 3, third full paragraph, to read as follows:

- fluorangiography is performed by [means of the] intravenous injection of a fluorescent substance and subsequent photography of the retina at different times. [Due to] As a result of blood circulation, [in fact,] the fluorescent substance arrives at the retina, where it colours the arteries, the capillaries and the veins [and thus], render[s]ing them [visible, as also] and the functional state of their walls visible;

Please amend page 3, fourth full paragraph, to read as follows:

- visus examination [permits a valuation of] allows visual acuity to be evaluated and [consists of] involves the patient's reading of letters [of] having different sizes at a distance of about three met[r]ers.

Please amend from after the fourth full paragraph on page 3 to before the first full paragraph on page 4 to read as follows:

Although retinitis pigmentos[a]is was identified and classified ~~about midway through last century~~ as a disease more than fifty (50) years ago, [very] little concrete progress has [so far] been achieved thus far, either [on the front of] with respect to possible cures or [on the] equally important on the front of understanding the causes that determine and regulate its course. Currently, [T]he [lines at present] most widely followed [by international] research internationally are: (i) the genetic approach, which seeks to identify the gene or genes responsible for the illness [and thus permitting a] for subsequent intervention [by means of] through modern genetic engineering techniques[.]; (ii) the transplant approach, an objective of which [aims at] is to perfect[ing] a technique that would make it possible [the] to transplant [of] retinal tissue or, at least, [the] graft[ing of] healthy cells into diseased retinas[.]; and (iii) the immunological approach, which [sets out to verify some] develops and investigates theories that [assume] what underlies the illness [to be underlain by] is some alteration of the immunological system.

Please amend page 4, first full paragraph, to read as follows:

#### **OBJECTS AND SUMMARY OF THE INVENTION**

Accordingly, it is an object of the present invention to provide a pharmacological composition in the form of a kit for effective and efficient treatment of retinitis pigmentosis.

Please amend page 4, second full paragraph, to read as follows:

Another [purpose] object of the present invention is to [furnish] provide a method of treating retinitis pigmentos[a]is that [will permit a] allows gradual recovery of visual acuity and enlargement of the field of vision, the sharpness of images, [and] the perception of colo[u]rs, and the [reconstitution] resurrection of a normal electroretinogram [in the long run] over time.

Please amend page 4, third full paragraph, to read as follows:

According to one aspect of the present invention, ~~these aims are attained by means of the use of particular~~ selected enzymes [for] are incorporat[ion]ed in a pharmaceutical composition [in kit form to be employed] for treating retinitis pigmentos[a]is by [means of] injecti[o]ng the enzyme incorporated composition into the retrobulbar tissue, ~~all as specified in Claim 1~~ of a patient's eye.

Please insert the following new paragraphs after the third full paragraph on page 4:

- - According to another aspect of the present invention, there is provided a pharmaceutical kit for treatment of retinitis pigmentosis which comprises the enzymes glutathione peroxidase (Enzyme A), prolidase (Enzyme B), glucose-6-phosphate dehydrogenase (Enzyme C) and, optionally, aldose reductase (Enzyme D) in aliquot parts

and interactive quantities appropriate for administering: (i) Enzyme A at a concentration generally within a range of 0.03 U.I. and 0.05 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye; (ii) Enzyme B, starting from the month following the last administration of Enzyme A, at a concentration generally within a range of 5 U.I. and 7 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye; (iii) Enzyme C, starting from the month following the last administration of Enzyme B, at a concentration generally within a range of 7 U.I. and 9 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye; (iv) Enzyme D, starting from the month following the last administration of Enzyme C, at a concentration generally within a range of 5 U.I. and 7 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye.

In accordance with a further aspect of the present invention, a method is provided for producing a pharmaceutical kit which comprises the enzymes glutathione peroxidase (Enzyme A), prolidase (Enzyme B), glucose-6-phosphate dehydrogenase (Enzyme C) and, optionally, aldose reductase (Enzyme D) for treatment of retinitis pigmentosa by injection into a patient's retrobulbar tissue, the method comprising the steps of providing the enzymes in aliquot parts and in interactive quantities appropriate for administering: (i) Enzyme A at a concentration generally within a range of 0.03 U.I. and 0.05 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly



intervals, for about three months and for each eye; (ii) Enzyme B, starting from the month following the last administration of Enzyme A, at a concentration generally within a range of 5 U.I. and 7 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye; (iii) Enzyme C, starting from the month following the last administration of Enzyme B, at a concentration generally within a range of 7 U.I. and 9 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye; and (iv) Enzyme D, starting from the month following the last administration of Enzyme C, at a concentration generally within a range of 7 U.I. and 9 U.I. in about 0.4 ml of physiological solution for approximately three consecutive days, at monthly intervals, for about three months and for each eye. - -